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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,326	09/18/2000	Paul Habermann	02481.1693	4393

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WASHINGTON, DC 20005

EXAMINER
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SCHNIZER, HOLLY G

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/24/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action****FILE COPY**

Application No.

09/664,326

Applicant(s)

HABERMANN ET AL.

Examiner

Holly Schnizer

Art Unit

1653

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 07 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: 8.Claim(s) rejected: 6, 7 and 9.

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

*Christopher S. F. Low*  
CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Continuation of 3. Applicant's reply has overcome the following rejection(s): The rejection of Claims 6-9 under 35 U.S.C. 112, second paragraph has been overcome by amendment; the rejection of Claims 6-8 under 35 U.S.C. 112, first paragraph for lack of enablement has been overcome by amendment..

Continuation of 5. does NOT place the application in condition for allowance because: the amendments do not overcome the rejection of Claims 6, 7, and 9 under 35 U.S.C. 103(a) as obvious over Achstetter et al. in view of Schmid et al. for the reasons stated in the previous Office Actions (see pp. 8-11 of Paper No. 13 for example). Applicants arguments that there is no motivation to use the yeast signal peptides of Aschtetter et al. in the system of Schmid et al., which is optimized for E. coli signal peptides, is not convincing because, as addressed in the previous Office Actions, the claims are not limited to the type of signal peptides that are used in the method. Applicants argument that Schmid et al. teach away because they teach that the yield in E. coli is relatively low and the isolation processes are complicated is not convincing. Applicants reference to low yield and complicated isolation processes is in reference to the art prior to Schmid et al. patent. Schmid et al. as a whole teaches that expression in E. coli can be dramatically improved and isolation processes simplified. Thus, as stated in the previous Office Action, one of ordinary skill in the art at the time of the invention would have been motivated to adapt the method of selecting signal peptides for the secretory expression of hirudin described in Achstetter et al. to be used in an E. coli system as described by Schmid et al. because Schmid et al. state the cultivation of yeast cells takes much longer and is more demanding than bacteria and because Schmid et al. show that the expression methods taught therein are highly successful in producing high concentrations of active Ala-hirudin. ..